The Suno India Show

Why are most of the medicines being approved for COVID-19 so expensive?

"Patents are given to pharmaceutical products, only if they are novel most of the pharmaceutical drugs are not really novel. We are now opposing some of the key drugs for which patent applications have been filed, giving reasons why this patent application should not be given a patent because it is not novel. And as we are seeing in COVID also they are repurposing the old drugs but the prices on these are still very high."

There is jubilation that Indian companies are all going to be producing this drug after getting a license or a voluntary license from Gilead, and they will be selling it in the Indian market but under the voluntary license Gilead will actually control from where they will buy the active pharmaceutical ingredient. And all of this actually increases the cost of the medicine. So the entire therapy could cost anywhere between Rs30-35,000 just for Remdesivir, Rs 30,00-55,000 for Favipiravir, Rs30,000-32000 for itolizumab. So these prices are high because there are only these few, one, two manufacturers who are producing this drug and who have patents on it.

"These are old drugs, and the company has probably already recovered the cost of research and other investment. The price of a five day course of Remdesivir in India is Rs 30-32000. The price should be the cost of active pharmaceutical ingredients plus the cost of production. And you can add a 10% profit. Plus taxes. A 10 day course of Remdesivir should not be priced at more than $9 or Rs 675."

"It is the patents on all these drugs, which is the biggest hurdle in bringing the prices down. And the second is the profits that the pharma companies want, even in a crisis situation like this and the entire world is almost in an ICU."

"The government has the power under the Patents Act under which they can say, well, this is an emergency and revoke patents on all of them. There are other generic manufacturers who can get into the market and produce these drugs and there will be competition.

"For remdesivir, The Cancer Patients Aid Association has written a letter to the government asking them to revoke it because it's not novel, it's not inventive plus it's an emergency but of course the government has not responded."

"So the government can issue compulsory licenses to generic manufacturers who are willing to make these medicines."

"The government can control the prices of these medicines under the drug price control order."

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Sandhya Srinivasan: *There is an urgent need to find a cure for COVID-19. Old drugs that have been developed and approved for one disease are now being evaluated to see if they can be used to reduce the severity and to bring down mortality of this new disease. Some*

drugs have been proven to be effective. Some have been found to have limited impact. Yet others have not been proven effective but are widely used anyway. All but one of these drugs is priced in the tens of thousands of rupees per course of treatment out of reach of most patients of COVID-19. Add the charges for other drugs and for the hospital. Families of patients are looking at bills of lakhs and lakhs of rupees. The bulk of people falling ill with COVID-19 are the poor and most vulnerable to infection because of their cramped living conditions, or because their work requires interaction with the public, such as frontline healthcare workers, bus conductors, shopkeepers, street vendors. But their doctors have told them that these drugs work. So they are among those standing in long lines outside pharmacies, for medicines which cost Rs 30,000 upwards.

Why are these medicines so expensive?

Hi, I am Sandhya Srinivasan, consulting editor of the Indian Journal of Medical Ethics and the host of this episode of The Suno India Show. This episode is part of a special COVID Science series where we bring in discussions with leading scientists, virologists among others.

In the previous episode with Dr Amar Jesani, we discussed the ethical considerations in conducting vaccine research, in particular research using controlled human infection. One element of research ethics, whether on vaccines or on drugs, is in access to approved drugs after trial. Why are most of the medicines being approved for COVID-19 so expensive? Our guest today Advocate Veena Johari, will answer this question and more.

Advocate Veena Johari has worked for decades on legal action to get access to affordable medicines, starting from HIV drugs, to cancer medicines, and now the drugs for COVID-19. Her consultancy firm, Courtyard Attorneys, is participating in a project against unjustified patents. They file third party observations against patent applications made by pharmaceutical companies at the level of the World Intellectual Property Organisation. She recently wrote a letter on behalf of the Cancer Patients' Aid Association to revoke a patent on Remdesivir.

Until 2005, India's Patent Act recognised only patents on the process by which something is made, not the product itself. And India had a huge generic drug manufacturing industry and made medicines for the entire world at affordable prices. The amended law recognises product patents. The result is the company that has the patent for a drug has the monopoly right to manufacture and sell the drug. No other manufacturer may do this without the patent holder's permission. Patents are a barrier to accessing affordable medicines. Access to affordable medicines is currently a very big issue.

When a company files an application for a patent in India, it is claiming that it has made an innovation that deserves a patent. Advocate Johari argues that most applications don't deserve to get patents. Her group has been involved in battles against patent applications of

many drugs for cancer, diabetes, and other conditions. They examine patent applications and if the innovation for which a patent is filed is not novel and inventive, they file a pre-grant opposition. They may also file an opposition even after a patent is granted. The Indian government also has powers to revoke patents so they can bring down the prices of the medicines and encourage competition.

Sandhya Srinivasan: *You have mentioned the WTO, TRIPS, patents and the generic industry. Could you explain these?*

Veena Johari: Okay. So WTO is the World Trade Organization, and it formulated what is called as TRIPs agreement, which is the Trade Related Intellectual Property Rights Agreement. And India is a signatory to this agreement. Now, in fact, in the agreement, we agreed that we will change our laws in India to come out with a product Patent's regime for pharmaceutical products. Okay! So, prior and because India is a developing country, so this agreement was signed in 1993, and it was effective from 1995. But because we are a developing country, we had 10 years to change our laws. So by 2005, we had to change our laws to cater to the TRIPs Agreement India had signed upon. Now, prior to this, we had a very good law, which did not allow what product patents on pharmaceutical products. So we only had a process. So what is the process patent? It is like, say, say we have a pen and the pen consists of there is a body, there is a refill, and a cap. Now, the way I put all this together, I would first put the refill into, into itself. And then I will put on the cap. Now this is a process of making a pen. Now this process can be patented, earlier but the product, this is the final product, which is a pen, you could not have patented, just to put it in very simple language. Okay but now after the change in the regime, even the pen itself, right, the drug itself is patented. So this drug cannot be made by someone else. Like this, I can use a different process and make the same drug I could make. I could just make the same pen in another process. Okay. As long as I didn't use the process that is patented but now I can't even make the pen itself. So earlier we, because we did, we had only processed patents. We had a huge generic industry, which is the generic industry. We have a lot of drug manufacturing industries in India. We were all using different processes to make the same drug. And therefore there was competition and the drug prices were very low, but now because the product has been patented, a lot of the drug manufacturers now are unable to make this product without infringing the patent of the patent holder. Now, if you infringe it, there will be court cases like the patent holder will file a case on the drug company that is its engineer, it will be a long drawn legal battle. Right!

Sandhya Srinivasan: *So before 2005, Indian manufacturers were required to respect process patents, on how something is made, but not product patents, i.e. the product itself. The patent regime changed in 2005. Indian drug manufacturers must now get a patent from the*

original company in order to manufacture a drug over here. Prices are determined by the patent holder. And they are very, very high. What are you doing to change things?

Veena Johari: So what we are doing is like, see we have to accept that our law had to change it as for the TRIPs agreement. But the important thing is that the patents are given to pharmaceutical products, only if they are novel, meaning if they are absolutely new and you invent it, like it's a real invention that you are coming up with now, you know that most of the pharmaceutical drugs, are not really invented again, not really novel. You know, they are old drugs in which they tweak a bit, they add something to it, which are all known things, and then they can like file a patent on it. Right? So what we are doing is we are now proposing some of the key drugs for which patent applications have been filed, giving reasons why this drug, this patent application should not be given a patent because it is not novel. It is not invented. There is enough in the public domain that shows that this drug can be manufactured easily, there is nothing new in it. Okay. And as we are seeing in COVID also, they are only repurposing the old drug at the moment, no one is really coming out with new drugs as such. Okay. So they are repurposing the old drugs but the prices on these are still very high. Right.

Sandhya Srinivasan: *So patent holders of old drugs are filing patent applications after making minor changes to the medicine. And your work is using provisions in the law to oppose such patent applications – they do not deserve a patent because there is no novel change in the medicine. How many drugs have been approved for COVID-19? And under what regulations have they been approved?*

Veena Johari: Okay. So actually, as of today no drug has got complete approval as such for COVID. All that has been granted is approval for emergency use. So emergency use is not really a full approval. So generally when the Drugs Controller, you know, gives approval for a drug, it goes through a phase 3 trial. And after the efficacy and safety, the drug controller gives approval for a particular drug. Now, sometimes we can give a waiver of phase 3, if the drug has been proven to be effective in some other country through a phase three. Or if it's some, if it's a drug, which is of a, of an unmet need as such, meaning that it's a life threatening disease, or there is one other drug which can cure the disease at hand, or if it's a life threatening disease, then the drug controller can use its power to give approval to drugs which are, you know, indicative of being useful. So in that sense, they have given emergency use to about five drugs as of today for COVID-19. They have given it to Remdevisir, to favipiravir, to dexamethasone and recently to itolizumab. So these are the five drugs, which the drug controller has said you can use in an emergency but the trials , full trials are still awaited. So either phase 3 and phase 4 are still awaited, because they, it's such an emergency situation today. So many people are getting affected by it, so they have allowed the use of these drugs for COVID patients. Now the Drugs Controller under Drugs and Cosmetics Act and under New Drugs and Clinical Trials Regulations that the Drugs

Controller has power to give approval for a manufacture of unapproved drugs as such or drugs for life threatening diseases.

Sandhya Srinivasan: *So the drugs you mention have been given emergency use approval because of the urgent need for treatment of a life-threatening disease. These drugs have not completed all the required three phases of trials for safety and efficacy.*

Veena Johari: These are all drugs that have been repurposed. Okay. So these drugs were approved for other conditions. Like Remdesivir was, earlier tried for Ebola. But it didn't work, or it was tried for Hepatitis C when it initially had come but it could not ensure efficacy in those two diseases, but they have done a kind of a RCT for Remdesivir in the USA. And they have got some kind of approval over there then based on which they have given over here. Ofcourse, the Solidarity trials do include Remdesivir in one of its arms. But these drugs are being repurposed in the sense that they have already got prior approval, through a phase 3 trial. And they are being useful in particular conditions. But now they are being repurposed for COVID, so whether it is efficacious in COVID or not, those kinds of trials need to take place to show that it is really efficacious. So they have done a Phase 2 trial, or, and some of them are doing a Phase 3 or some might, uh, the Drugs Controller as in Itolizumab, they have given a waiver to Phase 3 and they have asked them to do a phase four trial because it is an approved drug. So the Phase 4 would actually be like a Phase 3 because you have to show that this drug really works in a larger, larger population. Right? So that is how it is. But as far as safety is concerned, I think these drugs now, because they are already approved earlier they are known to be safe, but how efficacious for COVID is not determined yet completely.

Sandhya Srinivasan: *So in the case of a drug that has been repurposed for COVID, it is essentially a new drug, even though it's been approved for other purposes. And because it's a new drug, uh, the correct practice would be to, for it to compete a phase three trial for safety and efficacy. But because of the emergency situation, these drugs are approved for emergency use currently.*

Veena Johari: Yes, that's right. Absolutely. So all these repurposed drugs, if you find a new use of a known drug, it is defined as a new drug under the Drugs and Cosmetics Act. And so they have to go through the process of Phase 3 and then Phase 4.

Sandhya Srinivasan: *How much do these drugs cost for the entire course? Is the government covering any of this cost for any patients?*

Veena Johari: So these drugs are actually very expensive and why they are so expensive is probably because most of them are patented drugs. The only drug, which does not have a

patient on it is dexamethasone, which is actually very cheaply available in the market. And it is also because it doesn't have a patent on it. Now, Remedesivir, Gilead has a patent on it in India and Gilead has three patents on this drug. Okay. So their first patent is, uh, you know, their application. What they do is when they discover something, they do a very broad kind of application, which would cover everything under the sun.

Sandhya Srinivasan: *You mean patent application, right?*

Veena Johari: Yes, yes. patent application, which they filed before the patent controller. So that is a very broad kind of a macro structure, kind of a patent application where you can do many kinds of permutations and combinations in a particular compound. They have granted the patents for that. Then in 2016, another patent was granted for remdesivir in 2019. And in February of 2020, they have gotten another patent, which is specifically for Remdesivir and some other forms of the compound. Now, Gilead has got this patent and it is actually a very old compound okay. Because they were trying it for, for hepatitis C and for Ebola. So it's actually an old drug , but they have still got patents on it, uh, even though there is no novelty or there's no inventive step as such and they are going to sell now, they have entered into voluntary licenses with about four to five Indian companies. So there is Hetero, there is Cipla, then there is Jubiliant, so they are all going to be producing this drug after getting a license or a voluntary license from Gilead, and they will be selling it in the Indian market. And in other countries also but under the voluntary license Gilead will actually control from where they will buy the active pharmaceutical ingredient , because generally these licenses are very secret. They are not in the public domain, like generally these licenses control the geographical area where the manufacturer can sell the drugs and they generally control it from where they will buy the active pharmaceutical ingredient. And all of this actually increases the cost of the medicine. So Cipla and Hetero selling this drug in India today, and each vial of this drug, they are selling it between 5,000 to 4,500 to 5,400. That's the range of it. And classically, you know, you may need, uh, many of these vials. Uh, so the entire therapy could cost anywhere between 32 to 35 thousand just for Remdesivir. Then if we go to favipiravir, now favipiravir is also an old drug and Toyama Chemicals and Glenmark, they have had the patents of it, but they've just got patents recently that they have some other evergreen patents signed in it. Now they have reduced the price to 75, but they were selling it for 100Rs per tablet now per tablet you know that the dosage of this is pretty high in on the first day. You need to take about eight of these tablets. And then on the second day onwards, you need to take, you know, a slightly smaller number, which you have to go and take incur about 14 to 15 days. So this therapy can also come anywhere between 30 to 55,000, 53- 55,000, right. So this is again, it's very expensive for the common man. Then it's tocilizumab, Tocilizumab is also an injection and one injection costs somewhere around 45,000 to 60,000. Okay. It depends on what, how much of the dose you're putting in generally you need only one of this injection, but you may require two doses of it. And the recently given approval for Itolizumab that Biocon has been saying that they are going to sell it at 8000Rs per vial, and you may need one to four vials a case, it

depends on your condition. Now, again, that would then come to around 30-32000 for the entire therapy, right! So these prices are high because there are only these few one, one to two manufacturers who are producing this drug and who have patents on it.

Sandhya Srinivasan: *Researcher Andrew Hill has calculated the cost of production of some of these drugs which are off-patent. These are old drugs, and the company has already recovered the cost of research and other investment. The price should be the cost of active pharmaceutical ingredients plus the cost of production. And you can add a 10% profit. A 10day course of Remdesivir should not be priced at more than $9, or Rs 675. The price of a course of Remdesivir in India is Rs 30-32000. That's how affordable these drugs can be made. Except that these prices are controlled by big pharma. Is the government covering the costs of these drugs for any patients?*

Second, in emergency use you are effectively collecting information on the drug's use before it gets final approval. Is there a case for saying the government should ensure that these drugs, when used for emergency purposes, should be provided free to patients?

Veena Johari: So when these drugs are used in a clinical trial, they have to be provided free to all the participants of the trial, but the government is not providing these medicines free, of course, under any programs. So basically, the patients would have to purchase these medicines. So even in government hospitals, unless the government purchases these drugs and provides it free of cost to the patients who are enrolled in the government hospitals, they will have to buy it. And I don't see them doing that really other than, you know, allowing a trial to take place and then let the patients get it free of cost in the trial. And your second question is what can be done to see an emergency use it just obviously even the government doesn't know whether this is working or not. And so whatever patients are being enrolled, uh, the sponsor has to keep details of how this drug is working and submitted before the Drug Controller, on a periodical basis. Okay. And based on the data on the larger data, they will get only then they get complete approval for use. So what you are saying is right, actually that they should be provided free of cost, but they are not going to do that. So what are the options that the government has, the government can at least feel for the options in their hand to bring down the prices of these drugs.

Sandhya Srinivasan: *You have identified the major reasons for high drug prices. What can the government do to bring drug prices down?*

Veena Johari: The biggest hurdle is the patents on these drugs, right! Because the ones that are off patents are easily available, like most of your antivirals and antibiotics and dexamethasone, which are being used as a standard of care even hydroxychloroquine, in fact they are very cheaply available, but it is the patents on all these drugs, which is the biggest hurdle in bringing the prices down. And the second is the profits that the pharma companies want, even in a crisis situation like this and the entire world is almost in an ICU as

you may say it, but they are still thinking of their profits. They are still thinking of how we should gain on this because there is no cure. So anything will go, people will sell their jewellery, they will sell their homes, sell whatever it is to get medicine which may show even a little bit of hope. And you have seen this, that, uh, we have, uh, we have a history of quacks in our country, who had capitalized on HIV in the past, where they have sold drugs or some kind of therapy saying that this will cure you of HIV. Unfortunately, it is the pharma companies who are doing it today, who are supposed to follow certain rules and guidelines and whatever it is, and not to do these kinds of things, but that profits are still before the patients. And in fact, it is quite shocking, as you mentioned, right in the beginning that they are saying, well, if it can save you time for being in the ICU and the expenses that you would have to pay for the ventilator, and you might as well pay for the drug, that is not how drug pricing is done. You don't calculate prices of a drug based on how much you save by not being in the ICU or by not being on a ventilator. You calculate the prices as per your costs. You may make a 10%, or a 20% profit, but you cannot take this kind of 400% and 600% profit, which the pharma company or the pharma industry is known to take. So the government has a lot of powers, if they want to use it, they can, okay. One is they can revoke all these patents. They have the power under the Patents Act, in fact, in India under which they can say, well, this is an emergency on the public health. We are required to revoke these patents and they can revoke patents on all of them. The moment they revoke it, there are other generic manufacturers who can get into the market and they can produce these drugs and there will be competition and the prices will come down. So that is one thing that they can do. And in fact, for Remdesivir, Cancer Patient Aid Association has written a letter to the Government that you please revoke it because it is not novel it is not inventive plus it is an emergency, you have the power to remove it, so please do it but of course the government has not responded also. And I don't even know if they would be doing it or not. The other thing that the government can do is for patents, which have been granted for more than three years back, they can issue what is called a compulsory licence. So any other drug manufacturer can make an application to the government saying that look, I can make this particular drug and I can sell it at half the price or just for one thousand rupees for the entire therapy or just for a few thousand rupees for the entire therapy. You give me a compulsory license, I will produce it and I will make it available. Okay. So the government can issue compulsory licenses to generic manufacturers who are willing to make these medicines, but we don't know who is willing. The government can also through the public sector undertakings, give compulsory licenses. Unfortunately, a lot of the public sector undertakings have been shut down. And the third thing that the government can do is control the prices of these medicines under the drug price control order. The drug price control order generally has a list of essential medicines on it which are off patent. So those drug prices they control and they put a cap on it and they say, you cannot sell it for more than this particular amount, but even in an emergency, I mean that you first revoke the patents, even if you don't revoke that you say well we are going to cap the prices of these medicines, because you are selling it a way high cost, 50,000 - 60,000 is not affordable by people of this country. And so we are going to cap it and they can cap it and put it at an

affordable price for the people to access these medicines at affordable rates, or even the government can be a bit, you buy it and give it to the people free of cost, but it should be at an affordable price. Right! So these are the three things that the government can do, but they should have the will to do it.

Sandhya Srinivasan: *Will this patent regime have any impact on our access to the vaccines being developed for COVID-19?*

Veena Johari: So vaccines I think, the government and the manufacturer will generally get to an agreement, if they, if the government decides that they are going to get the procure the vaccines and then distribute it among the people in country, but the patent issue is that if, if they have filed a patent application for these vaccines, they may even get it. Okay. We don't know because the way patents are granted, we don't know when, when they will get it? Like, so it depends on what are the vaccines that they are coming out with. What is the compound in it, what does that come from? What are they trying to do? And are they trying to get a patent on these vaccines? If they decide to get a patent on these vaccines, then obviously they will try and control the distribution of it and they will give it only to a few countries or to a few people who can afford it. Like if the government decides that we want to get this vaccine for our people, then they can get into agreement with the manufacturer and procure it and negotiate the price on it and make it available to the people in this country. That is how the vaccine would work, because you would need to vaccinate a large population so that you get the herd immunity or whatever from the vaccination.

Sandhya Srinivasan: *The government has an interest in keeping vaccine prices down because the vaccines are used for large populations, for community benefit, and drugs are used for individual benefit for which the government need not really care.*

The patent regime is the reason why drug prices are so high. Advocacy organisations are opposing patent applications that are not justified. The law gives the government the power to bring down the prices of life-saving drugs. India was once the pharmacy of the world. It's time we got that title back.

Thank you very much, Veena Johari.

Thank you for listening to this episode of The Suno India Show. You can listen to this episode on sunoindia.in or any podcast app of your choice.